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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,226	04/07/2004	Inga Reynisdottir	2345.2049-005	6927

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HAMILTON, BROOK, SMITH & REYNOLDS, P.C.
530 VIRGINIA ROAD
P.O. BOX 9133
CONCORD, MA 01742-9133

EXAMINER	
BAUSCH, SARAE L	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 12/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/820,226	REYNISDOTTIR ET AL.	
	Examiner	Art Unit	
	Sarae Bausch	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-52* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 3, 6, 30, 39-45, drawn to method of diagnosis Type II diabetes by a polymorphism, classified in class 435, subclass 6.

II. Claim 2, drawn to method of diagnosis of Type II diabetes by polypeptide expression, classified in class 435, subclass 7.1.

III. Claim 4-5, 7-8, 31-35, drawn to nucleic acid, classified in class 536, subclass 23.1.

IV. Claim 9, drawn to method for producing a polypeptide, classified in class 435, subclass 68.1.

V. Claim 10, drawn to method of assaying for a polypeptide, classified in class 435, subclass 69.3.

VI. Claim 11, 13-15 and 17 drawn to method of identifying an agent that alters expression of a nucleic acid, classified in class 435, subclass 455.

VII. Claim 16 drawn to agent that alters expression of a nucleic acid, classified in class 536, subclass 24.5, for example.

VIII. Claim 18, drawn to identifying a polypeptide that interacting with a KchIP1 polypeptide, classified in class 435, subclass 500.

IX. Claim 19-22, drawn to therapeutic agent, classified in class 514, subclass 44, for example.

X. Claims 23-25, drawn to method of treating a disease by administration of a therapeutic agent, classified in class 514, subclass 44, for example.

XI. Claim 26, drawn to transgenic animal, classified in class 800, subclass 8.

* It is noted that claims 36-38, drawn to the use of a nucleic acid and claims 49-51, drawn to the use of a therapeutic were not placed in a group. It is unclear if applicant intends to claim a product (nucleic acid or therapeutic) or claim a process that requires a process step that includes the product (nucleic acid or therapeutic). If applicant amends the claim to indicate the claimed invention then the claims will be placed in the appropriate groups. If for example, if applicant amends claims 36-38 to recite a nucleic acid, the claims will be places in group III.

2. Claim 1, 27-29, 46-48 and 52 link(s) inventions of group I. The restriction requirement among the linked inventions is **subject to** the nonallowance of the linking claim(s), claim 1, 27-29, 46-48 and 52.

3. Claim 12 link(s) inventions of group VII (claim 16). The restriction requirement among the linked inventions is **subject to** the nonallowance of the linking claim(s), claim 12.

4. Claim 31-35 link(s) inventions of group III. The restriction requirement among the linked inventions is **subject to** the nonallowance of the linking claim(s), claim 31-35.

5. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection

are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

6. Further, should Applicants elect invention I, III, VII, and IX these group are subject to an additional restriction requirement as follows.

For election of group I, claim 3, applicant is required to pick a polymorphism from Table 13. Applicant is further required to pick a haplotype that encompasses the polymorphism from table 13 for claims 39-45. This is NOT an election of species.

For election of group III, applicant is required to pick a nucleic acid sequence from table 10.

Specifically, claims 3-5 and 39-45 claim distinct nucleotide sequences. Each of these sequences consists of a distinct nucleic acid sequence. Given the differences in structure and function, the Markush group of claim 5 and 39-45 is not a proper genus and therefore is subject to further restriction. A sequence search and non-patent literature search of these sequences would not be co-extensive with one another. Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning

of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequences are presumed to represent an independent and distinct invention, subject to restriction requirement pursuant to 35 USC 121 and 37 CFR 1.141. By statute, "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." 35 U.S.C. 121. Pursuant to this statute, the rules provide that "[i]f two or more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant... to elect that invention to which his claim shall be restricted." 37 CFR 1.142 (a). See also 37 CFR 1.141(a). Searching more than one of the claimed patentably distinct sequences represents a serious burden to the office.

For election of group VII, applicant is required to pick an agent listed in claim 16 that alters expression of a KchIP1 nucleic acid.

For election of group IX, applicant is required to pick a therapeutic agent listed in claim 19.

Specifically, claims 16 and 19 claim distinct sets of agents comprising antisense nucleic acid, polypeptide, nucleic acid receptor, binding agent, peptidomimetic, a fusion protein, an antibody, and a ribozyme. Each of these compounds are structurally and functionally distinct. For example, the antisense nucleic acid is composed of ribonucleotides linked by phosphodiester bonds. The polypeptide is composed of amino acids linked by peptide bonds and can assume complex tertiary structures. While the antibody is also composed of amino acids linked by peptide bonds, antibodies are glycosylated and their tertiary structure is unique, where four subunits (2 light chains and 2 heavy chains) associate via disulfide bonds into a Y-shaped symmetric dimer. Consequently, the reagents, reaction conditions, and reaction parameters

required to make or use each invention are different. Given the differences in structure and function, the Markush group set forth in claims 16 and 19 is not considered to constitute a proper genus, and therefore is subject to a further restriction requirement. A search of non-patent literature search for these agents would not be co-extensive with one another. For example, a search for an antisense agent would not be coextensive with a search for a peptdiomimetic. Further, a reference which renders obvious or non-novel the antisense agent would not also necessarily render obvious or non-novel the fusion peptide or peptidomimentic. Similarly, a finding that the antisense agent is novel and unobvious over the prior art would not necessarily extend to a finding that the fusion protein is also novel and unobvious over the prior art. Accordingly, a search of more than one of these agents as claimed in claims 16 and 19 presents an undue burden on the Patent and Trademark Office due to the complex nature of the search. Accordingly, Applicants are required to elect one (1) agent recited in claim 16 or 19. Note that this is not a species election.

The inventions are distinct, each from the other because of the following reasons:

7. Inventions of group I-II, IV-VI, VIII and X are biologically and functionally different and distinct from each other and thus one does not rend the other obvious. The methods of group I comprise steps which are not required for or present in the method of : polypeptide expression detection (group II) , culturing a host cell (group IV), contacting a cell with an antibody (group V), contacting a cell with a nucleic comprising a reporter gene (group VI), interacting two polypeptides (group VIII) and administration of a therapeutic agent (group X). The end result of the methods are different: detecting polypeptide expression (group II), producing a polypeptide (groupIV), assaying for a polypeptide (group V), identifying an agent that alters expression

(group VI), polypeptide interaction (group VIII) and treating a disease (group X) . Thus, the operation, function, and effects of these different methods are different and distinct from each other. Therefore, the inventions of these different groups are patentably distinct.

8. Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the nucleic acid of group III could be used to purify a nucleic acid, express a protein, or in situ hybridization which is not required for the method of group I.

9. Inventions I and VII, IX, XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions the method of group I does not require the products of group VII, IX, and XI.

10. Inventions II and III, VII, IX, XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions the method of group I does not require the products of group VII, IX, and XI.

11. The inventions of groups III, VII, IX, and XI are patentably distinct because they are drawn to different products having different structures and functions. The nucleic acid of group III is composed of deoxyribonucleotides linked by phosphodiester bonds and assumes the form of a double helix. The agent that alters expression of a nucleic acid of group VII, can be for example, a protein which composed of amino acids linked by peptide bonds and can assume

complex tertiary structures. While the therapeutic agent of group IX, can be for example an antibody which is also composed of amino acids linked by peptide bonds, antibodies are glycosylated and their tertiary structure is unique, where four subunits (2 light chains and 2 heavy chains) associate via disulfide bonds into a Y-shaped symmetric dimer. The product of group XI, is a transgenic animal which is composed of multiple nucleic acids, proteins, cells and organs. The products of groups III, VII, IX, and XI can be used in materially different processes, for example the DNA of group III can be used in hybridization assays, the therapeutic agent (antibody, for example) of group IX can be used in therapeutic immunoassays, and the agent (polypeptide, for example) of group VII can be used to make a fusion protein which alters expression levels, the transgenic animal of group XI can be used to assay a disease progression. Consequently, the reagents, reaction conditions, and reaction parameters required to make or use each invention are different. Therefore, the inventions of groups III, VII, IX and XI are patentably distinct from each other.

12. Inventions II and III, VII, IX, XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions the method of group I does not require the products of group VII, IX, and XI.

13. Inventions IV-V and III, VII, IX, XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions the method of group I does not require the products of group VII, IX, and XI.

14. Inventions VI and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the agent of group VI could be used to monitor disease progression, express a protein, or immunotherapy which is not required for the method of group VI.

15. Inventions IX and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the agent of group IX could be used to monitor disease progression or express a protein, which is not required for the method of group X.

16. Inventions VI and III, IX, XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions the method of group VI does not require the products of group III, IX and XI.

17. Inventions X and III, VII, are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions the method of group X does not require the products of group III and VII.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

18. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

19. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

20. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

21. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In

either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

22. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarae Bausch whose telephone number is (571) 272-2912. The examiner can normally be reached on M-F 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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Carla Myers
CARLA J. MYERS
PRIMARY EXAMINER

Sarae Bausch, PhD.
Examiner
Art Unit 1634